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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,077	11/20/2003	Dave Dickason	CP185B	8643

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EXAMINER	
KAROL, JODY LYNN	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
01/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,077	DICKASON ET AL.	
	Examiner	Art Unit	
	Jody L. Karol	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11/4/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 6-46* is/are pending in the application.

4a) Of the above claim(s) *22-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 6-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment/Remarks filed 11/4/2008. In view of Applicant's remarks, the finality of the previous Office action is withdrawn. Applicant's Amendment after final filed on 11/4/2008 has been entered. Claims 1 and 9 have been amended. Claims 4-5 were previously cancelled. Claims 22-46 remain withdrawn as pertaining to the non-elected invention. Thus, claims 1-3 and 6-46 are pending. Claims 1-3 and 6-21 are currently under consideration.

WITHDRAWN REJECTIONS

1. Applicant's arguments with respect to the rejection of claims 1-3 and 6-21 under 35 U.S.C. 103(a) as obvious over Murakata et al. (WO 88/07045) in view of Matthews et al. (WO 00/48571) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made and is presented below.

NEW REJECTIONS

2. After further consideration, the following rejections have been newly added:

Specification

3. The disclosure is objected to because of the following informalities: polyoxyl stearate is misspelled as "poloxyl stearate" throughout the instant specification (see in particular, page 10, line 3 and page 16, line 16).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 contains the trademark/trade name Mryj® 52. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a polyoxyl stearate and, accordingly, the identification/description is indefinite.

For examination purposes and in the interest of compact prosecution, Mryj® 52 will be interpreted as polyoxyl stearate.

Double Patenting

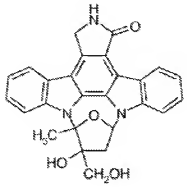
5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-3 and 6-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 and 23 of U.S. Patent No. 6,200,968 B1.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims (see claim 23 in particular) include compositions comprising a fused pyrrolocarbazole with the formula:



;

at least 20% (w/w) of polyoxyl stearate; and polyethylene glycol as claimed in the instant claim 1. Furthermore, the patented claims are also directed to compositions comprising 1 to 100 mg/ml or 1 to 50 mg/ml of the fused pyrrolocarbazole as claimed in the instant claims 2-3 (see patented claims 20-21).

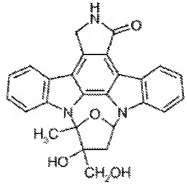
The patented claims do not claim the different molecular weights of polyethylene glycols as claimed in the instant claims 6-9 and 14-21, or the ratios of polyethylene glycol to polyoxyl stearate as claimed in the instant claims 11-13 and 15-21.

It would have been obvious to one of ordinary skill in the art at the time of the invention to optimize the molecular weight of the polyethylene glycol and the ratio of polyethylene glycol, or mixture of different molecular weight polyethylene glycols, to polyoxyl stearate. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 U.S.P.Q. 223, 235 (C.C.P.A. 1955).

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time it was made.

7. Claims 1-3 and 6-21 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 32-33 of U.S. Patent No. US 6,660,729 B1.

Although the conflicting claims are not identical, they are not patentably distinct from each other because patented claims (see claim 32 in particular) include compositions comprising a fused pyrrolocarbazole with the formula:



;

at least 20% (w/w) of polyoxyl stearate; and polyethylene glycol as claimed in the instant claim 1. Furthermore, the patented claims are also directed to compositions comprising 1 to 100 mg/ml or 1 to 50 mg/ml of the fused pyrrolocarbazole as claimed in the instant claims 2-3 (see patented claims 2-3 and 5-6). Patented claim 33 is directed to a composition comprising a polyethylene glycol 400 as claimed in the instant claim 6-9 and a 50:50 ratio of the polyethylene glycol 400 to polyoxyl stearate as claimed in the instant claims 11-12.

The patented claims do not claim a ratio of polyethylene glycol to polyoxyl stearate of 80:20, mixtures of different molecular weight polyethylene glycols claimed in

the instant claims 14-21, or the ratio of the different molecular weight polyethylene glycols to polyoxyl stearate as claimed in the instant claims 15-21.

It would have been obvious to one of ordinary skill in the art at the time of the invention to optimize the molecular weight of the polyethylene glycol and the ratio of polyethylene glycol, or mixture of different molecular weight polyethylene glycols, to polyoxyl stearate. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 U.S.P.Q. 223, 235 (C.C.P.A. 1955).

Thus, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time it was made.

Conclusion

No claims are allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jody L. Karol whose telephone number is (571)270-3283. The examiner can normally be reached on 8:30 am - 5:00 pm Mon-Fri EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Jody L. Karol/

Examiner, Art Unit 1617

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617